

Transposal Safety Station Technical Service Manual



Model No.: TP-SS100



Serial No.:_____

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Important Statements and Warnings



This symbol is used to alert the reader to important safety and precautionary information. When displayed on a device, it refers the user to accompanying instructions and identifies safety and precautionary information. For questions, please call Dornoch Medical Systems, Inc. at 1-888-466-6633.

Please read this manual and follow all instructions carefully. The words WARNING and CAUTION carry special meanings and should be carefully reviewed.

WARNING: The personal safety of the patient and/or user may be involved. Disregarding this information could result in injury to the patient and/or hospital staff.

CAUTION: These instructions point out special service or operational procedures including directions that should be followed to avoid damaging the device.

- WARNING: Before using this system, read and understand the information in this manual. Suction equipment should only be used by people that have had adequate training on the use of this type of equipment.
- WARNING: The Blood-borne Pathogens Standards, provided by the Occupational Safety and Health Association (OSHA), requires that all workers, having exposure to "potentially infectious materials", should wear the correct personal protection equipment.
- WARNING: To avoid the risk of electrical shock, this equipment must be connected to electrical outlet with a protective earth ground.
- WARNING: Verify all access doors are securely in place before operating this unit.
- WARNING: Only authorized service personnel should open any of the access covers on this equipment. User operation does not require access to these areas.
- WARNING: Use only Dornoch Medical Systems, Inc. approved accessories. Do not connect items to this system that are not designed for or specified for use with this system.
- WARNING: No user serviceable parts inside the unit. Contact Dornoch Medical Systems, Inc. customer service if an issue arises.
- WARNING: The unit is for use within the hospital and/or surgery center. The TPSS is not for field transport or field use. The unit should be moved by trained personal only; it is not designed as a portable devise.
- WARNING: No incline planes of operation.
- WARNING: This unit uses both bleach and enzyme in its operation. When re-filling reservoirs, always wear the appropriate Personal Protective Equipment.
- WARNING: This equipment is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide. Is not intended for use with AP or APG equipment.
- WARNING: Hot Water Temperatures higher than 120 °F can cause damage to the unit.
- There are no known significant risks of reciprocal interference posed by the presence of this equipment or its operation in either the operating room suites or other areas when used during specific investigations and/or treatments.
- There are no known potential electromagnetic or other interferences between this unit and other devices located and/or operated within the area of the operating room suites.

Déclarations et avertissements importants



Ce symbole sert à alerter le lecteur en lui procurant des renseignements relatifs à la sécurité et aux précautions à prendre. Lorsqu'il apparaît sur un dispositif, il renvoie l'utilisateur aux consignes jointes et indique la présence de renseignements relatifs à la sécurité et aux précautions à prendre. Pour toute question, veuillez téléphoner à Dornoch Medical Systems, Inc. au +1-888-466-6633.

Veuillez lire ce manuel et suivre toutes les consignes avec soin. Les mots AVERTISSEMENT et MISE EN GARDE ont des significations particulières, qui doivent être étudiées avec soin.

AVERTISSEMENT : La sécurité personnelle du patient et/ou de l'utilisateur peuvent être en jeu. Ne pas tenir compte de ces renseignements pourrait entraîner des blessures du patient et/ou du personnel de l'hôpital.

MISE EN GARDE : Ces consignes signalent un entretien spécial ou des procédures opérationnelles, comprenant des indications qui doivent être suivies pour éviter d'endommager le dispositif.

- AVERTISSEMENT : Avant d'utiliser ce système, il faudra lire et comprendre les renseignements inclus dans ce manuel. L'équipement d'aspiration doit seulement être utilisé par des personnes qui ont la formation adéquate pour utiliser ce type d'équipement.
- AVERTISSEMENT : Les normes relatives aux pathogènes transmis par voie sanguine et fournies par OSHA (Occupational Safety and Health Association), l'agence américaine pour la santé et la sécurité au travail, exigent que tout personnel exposé à des « matières à risque infectieux » porte l'équipement de protection individuel adapté.
- AVERTISSEMENT : Pour éviter le risque de choc électrique, cet équipement doit être connecté à une prise électrique protégée par une mise à la terre.
- AVERTISSEMENT : Vérifiez que toutes les portes d'accès sont immobilisées et en place, avant d'utiliser l'appareil.
- AVERTISSEMENT : Seul le personnel d'entretien autorisé a le droit d'ouvrir les portes d'accès se trouvant sur cet équipement. L'utilisateur n'a pas besoin d'accéder à ces lieux pour utiliser l'appareil.
- AVERTISSEMENT : Utilisez uniquement les accessoires approuvés par Dornoch Medical Systems, Inc. Ne raccordez pas au système des dispositifs qui ne sont pas conçus ni spécifiés pour l'utilisation avec ce système.
- AVERTISSEMENT : Aucune pièce se trouvant à l'intérieur de l'appareil ne peut être entretenue ou réparée par l'utilisateur. Contactez l'assistance à la clientèle de Dornoch Medical Systems, Inc. en cas de problème.
- AVERTISSEMENT : L'appareil est destiné à l'utilisation au sein de l'hôpital et/ou du centre chirurgical. Le TPSS n'est pas destiné à l'utilisation sur le terrain ni au transport sur le terrain. L'appareil doit uniquement être déplacé par du personnel formé ; il n'est pas conçu comme dispositif portatif.
- AVERTISSEMENT : Pas d'utilisation sur plans inclinés.
- AVERTISSEMENT : Cet appareil fonctionne avec de la javel et un produit enzymatique. Lorsque vous remplissez les réservoirs, veillez à bien porter l'équipement de protection individuel approprié.
- AVERTISSEMENT : Cet équipement ne convient pas à une utilisation en présence de mélanges anesthésiant inflammables avec air, oxygène ou protoxyde d'azote. Il n'est pas adapté pour l'utilisation avec un équipement AP ou APG.
- AVERTISSEMENT : Les températures d'eau chaude supérieures à 120 % risquent d'endommager l'appareil.
- Il n'existe pas de risque important connu d'interférence réciproque posé par la présence de cet équipement ou par son fonctionnement, que ce soit dans les blocs opératoires ou dans d'autres zones, en cas d'utilisation au cours d'investigations et/ou de traitements spécifiques.
- Il n'existe pas d'interférences électromagnétiques potentielles connues, ni d'autres interférences potentielles connues entre cet appareil et d'autres dispositifs situés et/ou utilisés dans la zone des blocs opératoires.

Introduction

The Transposal Safety Station (TPSS) is designed to empty, clean, disinfect and rinse reusable suction canisters. The TPSS also handles solids that are normally flushed down a clinical sink (hopper).

Two manuals are provided with this equipment and are shipped inside of the unit. Copies of these manuals are available to any Dornoch Medical Systems, Inc. (DMS) customer upon request.

The two different manuals are as follows:

Instructions for Use Manual – This manual is designed to instruct users in the correct operation of the TPSS as well as safety considerations associated with the unit.

Technical Service Manual – This manual includes operation instructions, installation & disconnection instructions, technical specifications, and preventative maintenance procedures for the unit.

This is the Technical Service Manual, and it is broken into seven sections including:

- Introduction
- Technical Description
- Operation
- Installation
- Maintenance
- Company Information
- Limited Warranty

As a supplement to these two manuals, instructional video(s) are available to assist maintenance personnel in their understanding of the equipment's operation and the maintenance procedures needed. If required, DMS service personnel can be contacted 24-hours a day at 1-888-466-6633.

Intended Use

The intended use of the TPSS is the automated handling of surgical fluids collected within the hospital and/or surgical center. Fluid filled canister(s) are automatically emptied, cleaned, disinfected and rinsed allowing for immediate reuse in the surgical process.

Equipment Description

The TPSS is a standalone unit that can automatically process up to two disposable or reusable canisters. The TPSS also disposes of solids that are normally flushed down a clinical sink (hopper) allowing it to replace an existing clinical sink when space restrictions apply. The TPSS significantly reduces employee exposure to potentially infectious body fluids, while eliminating up to 70% of Operating Room red bag waste.

The TPSS processes 1800cc and/or 2800cc canisters for reuse. Once installed, operators simply place fluid filled canisters in the unit and close the lid. With a touch of a button the canisters are automatically emptied, cleaned, disinfected and rinsed. The canisters are then placed in an area to dry. With the addition of a new single use lid, they are ready for reuse within the facility.

Technical Description

Specifications

The TPSS specifications are presented in Table 1 below. TPSS external dimensions and features are shown in Figures 1 and 2 on the following pages.

Item	Transposal Safety Station (#TP-SS100)
Certifications	Certified and Listed as a Class 1 Medical Device as
	authorized under the Medical Device Standard IEC
	60601-1 and IEC 60601-1-2 for EMC.
	Certified to CAN/CSA Standard C22.2 No. 601.1.
IP Certification Classification	IP 60
IAPMO Listed	IGC-238-2007
Patents	5,807,359; 5,931,822; 6,263,887; 6,368,310;
	6,588,436; 6,673,055; 6,776,175; 6,796,317
Installation	Fixed
Size (inch (cm))	36(91)W x 28(71)D x 48(122)H
Weight (lbs (kg))	260(118)

TABLE 1

Utilities	
Power	120VAC, 60Hz, 15amp (See Replacement Items for
	fuse specifications).
Water	3/4" Hot and Cold, 6.0gpm(22.7lpm), 55psi Hot Water Temperature 110 – 120°F (43 - 49 °C)
	Hot Water Temperature 110 - 120°F (43 - 49 °C)
Drain	2"
Space	37(94)W x 40(102) D x 66(168)H
Additional Cooling	None.
	This equipment is not suitable for use in the presence
	of flammable anesthetic mixture with air or with
Flammable Rating	oxygen or with nitrous oxide.

Operation

1	
Mode	Continuous
Cycle	128 to 210 seconds
Water Use	7.0(26.5) to 11.2(42.4) gallons(liters)/cycle
Enzyme Use	0.3(8.9) to 0.7(20.7) ounces(milliliters)/cycle
Bleach Use	3.4(100.6) ounces(milliliters)/cycle
Method of Sterilization	N/A

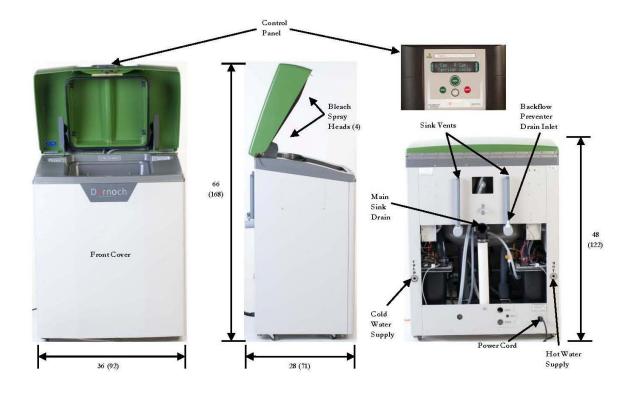


Figure 1 - Safety Station Dimensions and Features (Dim. = inch (cm))

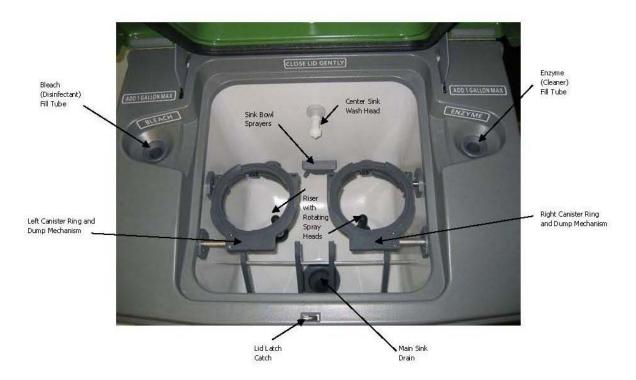


Figure 2 - Safety Station Sink

Operation

The TPSS (Figure 3) empties, cleans, and disinfects reusable 1800cc, reusable 2800cc (Figure 4) or disposable 1800cc suction canisters. This unit is ideally located in a decontamination room near the operating room suites.

When an instrument or DMS transport cart is unloaded in the decontamination room, one or two sealed canisters are placed in the TPSS. The operator then closes the TPSS lid and presses a button to start a patented disposal process.

With the TPSS lid locked, canister lids are removed and fluid collectors are emptied, cleaned, and disinfected using an array of spray heads. A hot water and enzyme solution cleans collectors. An inexpensive 2700 parts-per-million household bleach and cold-water solution then disinfects.



Figure 3 - Safety Station



Figure 4 - Reusable 2800cc Canister

Once disinfected, canisters are rinsed with cold water before the unit's lid unlocks and opens. Reusable canisters are then removed from the TPSS and allowed to air dry before reuse (Figure 5). Disposable canisters and lids are discarded. The entire process takes just a minute and-a-half per canister.

DMS has received a letter of approval from the Clorox Company for the use of Ultra Clorox Bleach (EPA Reg. No. 5813-50) as a disinfectant spray on reusable suction canisters. Independent lab testing data demonstrating the TPSS's ability to deliver a minimum 2700 parts-per-million disinfecting bleach solution is available upon request.



Figure 5 – Canister Drying Tree

Safety Features

The TPSS has numerous built in safety features including:

- **Closed System Design.** The TPSS is designed to confine and contain fluids during disposal. Personnel never open suction canisters.
- Interactive Controls. The TPSS's high-tech control system guides users through unit operation while monitoring key functions.
- **Disinfection Cycle Monitoring.** Continuous automatic monitoring of the disinfection cycle is accomplished with multiple electronic sensors within the TPSS unit.
- Vacuum Protection. Hydrophobic filters on each green Transposal single use lid prevent main line vacuum contamination. In addition, DMS's unique vacuum adapter only connects to protected lid vacuum ports.

Environmental Protection

Infectious Waste: None

Non-infectious Waste: After the TPSS disinfection cycle has been completed; the canister and the disposable are non-infectious.

Waste Disposal Accessories

There are no current accessories required for disposal from this unit.

MSDS Sheet for Bleach and Enzyme

MSDS sheets are available upon request by calling DMS at 1-888-466-6633.

Reusable Suction Canister Use and Processing

Canister Use. Transposal canisters, consisting of a reusable fluid collector and single use lid, shall be used in place of traditional disposable suction canisters/liners in surgery and other patient care areas throughout the facility. Transposal reusable canisters, like their disposable counterparts, are considered non-critical and non-sterile medical devices and should be handled accordingly.

Before starting a procedure, verify the canister is clean and has a new single use lid is installed. If unsure of the status of the lid, replace it with a known new single use lid.

Fluid collection for each canister is up to 2,800mL with an accuracy of +/- 50mL.

Canister Processing. Designated OR, SPD, or housekeeping personnel shall empty, clean and disinfect used Transposal canisters in the TPSS. Processing shall be accomplished in accordance with manufacturer's directions.

While handling canisters, personnel shall wear personal protective equipment (PPE). Minimum PPE includes gloves, mask, and eye shield.

Personnel shall wear clean gloves when removing processed canisters from the TPSS. Reusable collectors are always removed first and placed on a rack to air dry. After removing collectors, personnel shall remove single use lids and place them in regulated or non-regulated trash in accordance with facility policy.

Chemical Handling. Bleach and/or Enzyme should be added to the TPSS when notified that the chemical is low. Add up to one gallon maximum to the reservoir to prevent overfilling. While adding chemicals, personnel shall wear PPE.

If the bleach reservoir is allowed to run empty, the reusable canisters will not be disinfected at the end of the cycle.

Overflow Protection. The single use lid (#TP-DL2800) contains a white hydrophobic filter that serves as an overflow protection device. Once the canister is filled to capacity and the filter gets wet, suction within the canister will stop.

Only attach the black vacuum adapter from the suction source to the port labeled "vacuum supply" on the single use lid. The filter is located under this connection port.

Disinfection Verification. Daily visual verification of the TPSS disinfection cycle shall be completed using a Verification Log Kit (#TP-VL100). Continuous automatic monitoring of the disinfection cycle is accomplished with multiple electronic sensors within the TPSS unit. If an error is detected, corrective actions are displayed on the TPSS screen. All disinfection error messages shall be reported to an immediate supervisor.

Reusable Collector Storage. After drying, disinfected reusable collectors shall be transferred to a designated clean storage area.

Single Use Lid Storage. A supply of new single use collector lids shall be kept in a designated clean storage area with processed collectors, or near any point of use.

Canister Assembly. A new suction canister, consisting of a new single use lid and a dry disinfected reusable collector, shall be assembled in a designated clean area. When assembling canisters, the user should visually inspect the canister for any cracking or damage and replace it if necessary.

Canister Replacement. Prior to reuse of the canister, a new single use lid (#TP-DL2800) must be placed onto the clean canister. The user must verify the white hydrophobic filter is in place on the lid. Canister replacement procedures by department are presented below.

Surgery, Special Studies, GI Clinic, Labor & Delivery Departments. Suction canisters shall be replaced after every surgical procedure.

Med-Surg Floors, ICU's, Other Non-Procedure Areas. Suction canisters shall be replaced for every new patient or every 24-hours for the same patient.

Canister Transportation. Used canisters shall be sealed, securely placed in an instrument or DMS Transport Cart, and transported to the TPSS for immediate processing. Before placing canisters in to the TPSS, verify all of the ports on the single use lid are capped.

Canister Storage. Used canisters may be stored up to 24 hours in a DMS Transport Cart or other secure location prior to processing in the TPSS.

Instructions for Use

Processing Canisters:

Step 1 - Load Canisters into Unit (Figure 6)

Place a canister into the left or right ring. Turn the canister clockwise until it seats in the ring. Continue turning the canister clockwise until a "BEEP" is heard. The unit has the ability to process one or two canisters. If there is another canister that needs to be processed, place the second canister into the open ring and repeat the above process.



Figure 6 – Load Canisters

Step 2 - Start the TPSS (Figure 7)

Close the TPSS lid. With the lid closed, the control panel will indicate which rings are securely holding canisters with the message "L Can", "R Can", or "L Can R Can". Press the green "WASH" button once for normal operation. An extended cleaning cycle can be initiated by pressing the "WASH" button twice within five seconds.



Figure 7 – Safety Station Control Panel

Step 3 - Remove Canisters and Lids

When the canisters are finished processing, the TPSS Lid will automatically open. Remove each canister (Figure 8) by grasping the top rim and turning counter clockwise. Place canisters on a clean rack or drying tree (Figure 9) to air dry. Remove canister lids from the lid basket and discard according to hospital policy.





Figure 8 - Reusable 2800cc Canister

Figure 9 - Canister Drying Tree

Adding Bleach and Enzyme:

Please fill bleach and enzyme tanks (Figure 10) when an alarm sounds indicating a low solution level. Either "Bleach Low" or "Enzyme Low" will appear on the control panel display (Figure 7).

NOTE: Do Not add more than one gallon of fluid to solution reservoir.



Figure 10 – Adding Chemicals

Performing Verify Disinfection Cycle:

To verify that the unit is disinfecting, place the unit into the check for disinfection mode by using the following steps:

- 1. Place and lock two canisters into the rings.
- 2. Close the lid.
- 3. Press the "Wash Button" then depress the "Clean Sink" button twice.
- 4. The main display will indicate that the unit has gone into the disinfection test mode.
- 5. When the unit reaches the point in the cycle where the disinfection solution is on the canisters, unit will stop and alarm.
- 6. Press the "open" button to open the lid.
- 7. Use the test strips, included in the in service tub, to wipe the inside and outside of each canister.
- 8. If the test strip turns purple the canisters are being disinfected.
- 9. If the test strips do not turn a different color, call DMS at 1-888-466-6633 and ask for service.
- 10. 10. After testing is complete, close the lid to finish the processing cycle.

Clean Sink Cycle

To run a clean sink cycle and disinfect the unit's basin, verify that there are no canisters inserted into the unit's rings. Close the lid and press the "clean sink" button on the units control panel. The lid will open automatically at the end of the clean sink cycle.

Single Use Lids

The TP-DL2800 lid is designed to be used for a single patient. Failure to change the lid after each patient may result in the following:

- 1. Loss of available suction. Contaminated and/or wet filters will affect vacuum flow.
- 2. Cross contamination. Improper usage of single use items poses a health risk to patients and health care providers.

Exterior Cleaning and Disinfection

The exterior of the unit can be decontaminated by using an approved hospital grade disinfectant. It is recommended that Personal Protective Equipment (PPE) be worn at all times when doing so.

Storage Between Uses

The DMS TPSS requires no special shutdown or storage procedures between uses. It may remain plugged in and connected to water supplies.

Unit Information and Error Messages

The TPSS provides the operator feedback for common operating errors via the display panel. The most common messages are described below. The display can also display a unique numerical error code. Record this code before contacting customer service. Please call DMS at 1-888-466-6633 for assistance with any error message.

Warning or Error	Action Required			
Leak Detected: This message indicates that there has been a leak detected within the unit. The unit alarms at the end of the cycle when canisters have completed the cleaning and disinfection process.	Check all supply lines for correct connection. Call service if necessary.			
Remove Obstruction: This message provides notice that an obstruction has occurred while rotating one or both of the canisters.	Check basin for source of obstruction and remove it, if found. Call service if necessary. Reprocess canisters once problem is resolved.			
Bleach Low: This message indicates that the unit is running low on bleach. The unit alarms at the end of the cycle when canisters have completed the cleaning and disinfection process.	Refill unit with up to 1 gallon of bleach.			
Bleach Out: This message indicates that the unit contains no bleach for the disinfecting process. The unit alarms at the end of the cycle, but the canisters have not been disinfected.	Refill unit with up to 1 gallon of bleach and reprocess canisters. If error continues, please call service.			
Enzyme Low : This message indicates that the Enzyme solution is running low. The unit alarms at the end of the cycle when canisters have completed the cleaning and disinfection process.	Refill unit with up to 1 gallon of enzyme.			
Verify Disinfection: This message indicates that the unit did not detect the flow of bleach and that the canister may not be disinfected.	Refill unit with up to 1 gallon of bleach and reprocess canisters. If error continues, please call service.			

Troubleshooting Guide

Problem: Inadequate Cleaning of Canister Possible Solution:

- 1. Check drain. If the drain is slow or clogged, call maintenance.
- 2. Add one gallon of enzyme and/or bleach if indicated on TPSS control panel.

3. If a used canister has sat for a long period of time and fluids have dried onto the sides, or if a canister has contents which are very rich in whole blood, run a second cycle or long cycle. A long cycle is started by pushing the "WASH" button twice within five seconds.

Problem: Only One Side Cleans Possible Solution

1. Call DMS at 1-888-466-6633.

2. Continue to use operative side until repairs are made.

Problem: Unit Will Not Operate

Possible Solutions:

- 1. Check that the machine is plugged into an operational outlet.
- 2. Check and reset the ground fault switch for on the outlet.
- 3. Call maintenance to replace the Unit internal fuses.
- 4. Check that the TPSS lid is down and that canisters are locked in and registered on display.
- 5. Check for error display and review specific code for action. CALL DMS with six-digit error code.

Problem: The Unit's Canister Rings Did Not Go Back to Home

Possible Solution:

Call DMS at 1-888-466-6633. Use the opposite side until service is complete.

Problem: Error Code Displayed

Possible Solutions:

1. Write down error code(s). For more than one error code, press the abort button until all error codes are displayed.

2. Call DMS at 1-888-466-6633 with error codes.

Problem: Water on Floor Around Unit

Possible Solution:

Check plumbing and back flow preventer for leaks. Call maintenance for repair.

Problem: Strong Bleach Odors

Possible Solutions:

1. Improve area ventilation.

2. When changing bleach bottle, replace lid of old bottle before disposing of bottle.

3. Call DMS at 1-888-466-6633.

Symbols & Labels

The explanation and location of all Labels, Safety Signs, Symbols and Displays used on the equipment is presented below.



Protective Earth Ground Symbol – This label is used to symbolize a protective earth ground location on the unit. There is one located on the ground from the main power cord and another located on the ground for the 24VDC power supply.



Functional Earth Ground Symbol – This label is used to symbolize a functional earth ground. They are located near all functional grounds.



Single Use Symbol – This label is used to symbolize that the product is single use only. This label is located on the single use lid (TP-DL2800).

Electrical Requirements and Serial Number Label - Located on the back of the unit upper right corner (as facing the back). Information contained on this label: Dornoch contact information, serial number, ETL compliance information, patent information.

Dornoch Medical Systems, Inc. 200 NW Parkway Riverside, MO 64150 www.dornoch.com (888) 466-6633

Serial Number

This equipment complies with and is Listed under the IEC-60601-1 (2nd Edition) Standard for a Class 1 Medical Device.

Transposal Safety Station 115 – 120 VAC 60 Hz Nominal 2.0 – 4.5 A Momentary Peak 9.5 A

This equipment complies with and is approved for use under: IEC-60601-1: General Requirements for Safety IEC-60601-1-2: Electromagnetic Compatibility - Requirements and Tests

 Licensed under the family of United States Patents including patent numbers:

 5,807,359
 5,931,822
 6,263,887
 6,368,310

 6,588,436
 6,673,055
 6,776,175
 6,796,317



Power connection must be connected to a Hospital Grade power receptacle only.



CLOSE LID GENTLY

BLEACH

ENZYME

ADD 1 GALLON MAX



Operating Instructions – Located on the back of unit near the power cord. The label is used to instruct the user to the manuals as well as inform them of the power outlet requirements of the unit.

ICB Service Diagram - Located on the backside of the circuit board firebox cover. The diagram shows the location of electrical component inputs.

Close Lid Gently Label - Located on the top center of the unit's basin. It prompts the operator not to slam lid.

Bleach Fill Tube Label - Located on the top left-hand side of the basin. It informs the user of the correct location to add bleach.

Enzyme Fill Tube Label - Located on the top right-hand side of the basin. It informs the user of the correct location to add enzyme.

Add 1-Gallon Max Label- Located above the bleach and enzyme fill tubes on the top right and left-hand side of the basin. Advises the user of the limit for reservoir volume.

Control Panel – Located in the center of the front edge of the lid. It notifies the users of current processing information and any warnings or errors.

DMS Technical Service - Information

DMS Technical Service is available 24 hours a day, 7 days a week. Technicians are available in the office from Monday – Friday from 8AM until 5PM central standard time. DMS uses a paging system for any calls received at other time during the day and will get back with you as soon as possible. Please call 1-888-466-6633 and have the information below available for the technician. If possible, call with the equipment available for troubleshooting.

- Equipment Type (Ultra Duo, Ultra Quad, Evac or TPSS)
- Equipment Serial Number
- Description of the problem
- Location of the equipment
- Contact information for a service technician coming to the account

Accessories

The following is a list of accessories available for use with the TPSS.

- TP-DT100 Drying Tree
 - Allows for the inverted hanging of the reusable canisters for drying.
- TP-RS400 Four Collector Roll Stand
 - Holds up to four canisters for use in operating rooms during the collection of surgical fluids.
- TP-RS800 Four Collector Roll Stand
 - Holds up to eight canisters for use in operating rooms during the collection of surgical fluids.
- TP-RC1800 1800mL Reusable Collector
- TP-RC2800 2800mL Reusable Collector

Consumables

The following is a list of consumables associated with the TPSS.

- TP-DL2800 Single use Canister Lid
- TP-DCL1800 1800mL Disposable Canister
- TP-DCL2800 2800mL Disposable Canister
- TP-EZ100 Enzymatic Cleaner
- Clorox Bleach

Installation

Protective Packaging & Unpacking

Special measures are needed for and during transport of the unit. TPSSs are heavy and should not be lifted in or out of any position as personal injury could occur. Each TPSS is equipped with four casters and adjustable legs. TPSSs must be rolled into/out of position during installation/de-installation. Adjustable legs are lowered and seismic anchoring brackets attached (if required) to secure the unit in place.

A power lift is required for lifting the unit and safety methods are recommended.

To obtain information on transporting and temporary storage considerations call DMS at 1-888-466-6633.

Premature unpacking of the TPSS could risk damage to or loss of the installation items that may be sent with the unit. Contact customer service if unpacking the unit is necessary.

Site Preparation

A DMS Installation Engineer is responsible for the physical hook-up, on-site quality control testing and the initial start up of TPSS equipment. Customers are responsible for preparing the equipment space and utilities at the installation site.

All equipment sites must be prepared in accordance with the requirements described here at least seven (7) days prior to scheduled system installation.

This section outlines the general and specific site preparation requirements for space, water, drain, and electrical needs are presented below. Figure 11 shows a typical TPSS site preparation. Figure 12 presents an architectural drawing of site requirements. Please use these figures as a reference for proper site preparation.

Utilities Needed for Installation

Power	120VAC, 60Hz, 15amp
Water Supply	3/4" Hot and Cold, 6.0gpm(22.7lpm), 55psi
Hot Water Temperature	110 – 120°F (43 - 49 °C)
Drain	2"
Space (inch (cm))	37(94) W x 40(102) D x 66(168) H

Table 2

Space

The TPSS installation site must be a minimum of 37" (94cm) W x 40" (102cm) D x 66" (168cm) H (with lid open). TPSSs must be installed no less than 6 inches (15cm) from the wall to accommodate operator access to the unit's main power supply wall outlet.

Water Supply

Hot and cold water supplies are needed for TPSS operation. A 3/4" supply is desirable because of the volume of water it carries, but a 1/2" line is usually sufficient as long as the facility has good water pressure (55 psi or higher at the unit).

Hot and cold water supply pipes should run up or down the wall to the left side of the space where the machine will be installed, ending 48"(122cm) to 58"(148cm) from the floor. Attach a threaded ball valve to the end of each supply pipe. The ball valve must end with 1/2" fpt.

Hard water in excess of 5.0 grains per gallon can adversely affect equipment operation. Consequently, hard water must be treated before it enters installed equipment. Untreated hard water supplies will void equipment warranties.

Electrical

The unit's electrical supply must be within 36" (92cm) of the unit location. A ground fault receptacle rated at 120 VAC, single phase at 60 Hz and 15 amps is required. The TPSS draws a peak current of 9.5 amps with a normal operating current draw of 2.0 to 4.5 amps.

Sanitary Sewer (Drain)

The TPSS requires a minimum 2" PVC or copper sanitary sewer drain connection. The ideal drain is centered on the install site, 6" (15cm) to 15" (38cm) from the floor. The drain can protrude vertically out of the floor or horizontally from the wall. Drainpipes brought up through the floor should stay as close as possible to the wall. Wall drains should not protrude more than 6" (15cm) from the wall.

A positive drain connection is recommended. Running drain tubing to an open hopper or mop sink is not recommended. In addition, an indirect waste drain with an air gap is not recommended due to splash and splatter.

Existing Hopper Sink Replacement

A hopper can be removed, and its water and drain connections used for unit installation. A 1/2" FPT threaded ball valve must be installed on the end of the hot and cold water supply lines.

Please note before removing a hopper sink that the drain center can be no higher than 27" (68cm) from the floor. Standard 3" or 4" hopper drains meeting this height restriction are acceptable for unit installation. A DMS Installation Engineer will convert hopper drains for unit use during installation.

Backflow Preventers

Backflow Preventer (BFP) assemblies are available for purchase from DMS. One is used for hot water and one is used for cold water. The Backflow Preventers are Reduced Pressure Zone (RPZ) design. Each assembly consists of a strainer, water pressure regulator, BFP and pressure gauge. Each assembly is provided assembled and pressure tested. Wall flanges are included to secure assemblies to the wall. If the Customer is providing the BFP assembly, please contact DMS (1-888-466-6633 and select "Service" option) for component requirements of this assembly.

It is preferred that Backflow Preventers be installed by the Customer or Customers Representative to ensure compliance with local regulations. Upon Customer request, BFP assemblies are shipped early for Customer installation during site preparation. Otherwise, a DMS Installation Engineer installs BFP assemblies during equipment installation.

DMS recommends the BFP assemblies mount 48" (122cm) or higher from the floor so they are not behind the unit once it is installed. Also, the BFP assemblies should be within 36" (92cm) of the hot and cold water supply lines. These are general recommendations and the BFP assemblies need to be installed to comply with local codes. Assemblies should be horizontally mounted 10" (25cm) to 14" (36cm) apart from each other, and staggered vertically 2" (5cm) to 3" (8cm) for ease of maintenance.

A 3-foot high-pressure hose is provided with each BFP. DMS Installation engineers will have additional highpressure hoses of 3, 5 and 8-foot lengths to complete installation. These hoses connect BFP assemblies to the water supply as well as to the rear of the unit.

Finally, air gap basins on each BFP are connected to a TPSS sink vent pipe using flexible PVC hose (included). The Customer is responsible for the plumbing and sweating of all copper drainpipes if preferred or required.

Please note that BFP assemblies are required to meet plumbing code requirements. DMS provides these units to simplify Customer site preparation. The BFP assemblies are not considered part of the TPSS equipment. It is the Customer's responsibility to maintain and inspect BFP assemblies as required by local regulations.



Figure 11 – Typical Safety Station Site Preparation

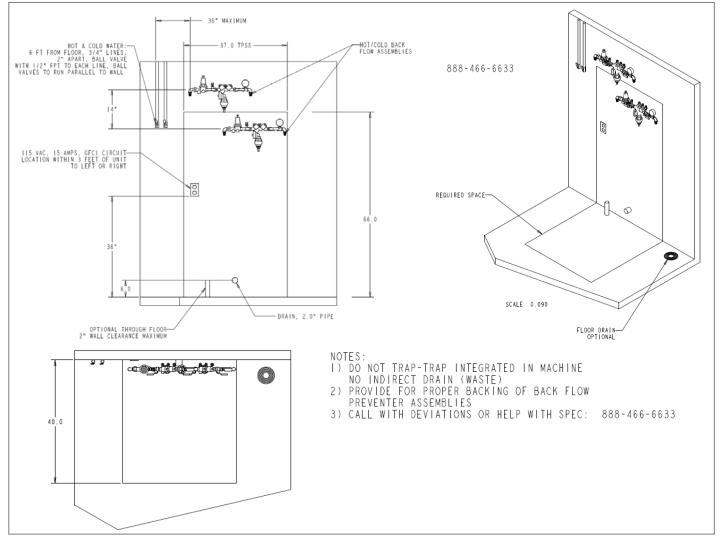


Figure 12 – Safety Station Architectural Drawing

De-install/Disconnect Instructions

Please contact DMS at 1-888-466-6633 prior to de-installation or re-installation of TPSS units.

If a Customer de-installs or re-installs a TPSS, the guidelines listed below must be followed.

- Always wear personal protective equipment (PPE), including eye protection and latex gloves, to prevent contact with potentially infectious material.
- Always unplug the unit from the wall electrical receptacle before moving equipment.
- Wipe down the unit with an approved contact disinfectant after each use.

Equipment Storage

Temperature range for proper storage is -20°C to 40°C. If unit is to be taken out of service and stored for a prolonged period of time, evacuate water from the hot and cold water manifolds, as well as removing the bleach and enzyme solution from their chemical tanks regardless of temperature within storage facility.

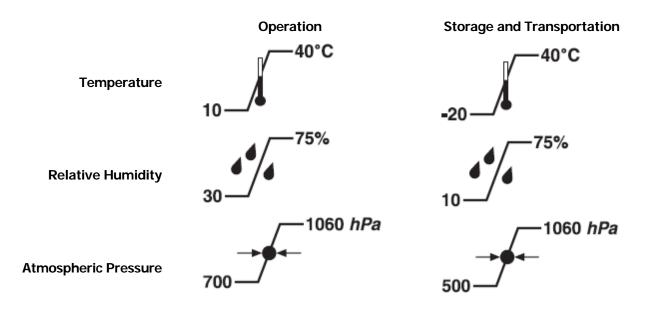


Figure 13 – Environmental Conditions

Maintenance

Qualifications for Service Personnel

Service personnel will be trained during the installation of the equipment on preventative maintenance, troubleshooting and common problems. Support for the service technicians is always available by calling Customer Service at 1-888-466-6633.

Qualifications needed to properly service products manufactured by DMS in no way allows for or authorizes any person to avoid the authorities with jurisdiction to impose additional requirements for qualifications on Service Personnel.

DMS recommends that all facilities service and healthcare professionals attend the Maintenance & In-Service Training sessions offered during the time of equipment installation.

All maintenance to be performed by qualified personnel only. Repairs by unauthorized individuals should not be attempted and may result in damage to or malfunction of the system or even personal injury.

Service Warnings

Warning: Modification of this equipment is not allowed.

Warning: When performing any service or maintenance procedures on the TPSS, follow all manufacturers' instructions.

Warning: Handling biohazard waste is potentially dangerous. Wear personal protective equipment when servicing or removing canisters from the TPSS.

Warning: Prior to performing any maintenance on the TPSS, run a clean sink cycle to disinfect the basin. On completion of the sink cycle, unplug the unit from the wall outlet. Not unplugging this unit will leave dangerous voltages & current accessible to the service personnel working on or in this machine.

Note: If the unit is to be moved, wipe down the outside of the unit with an approved hospital grade contact disinfectant.

Note: Remove all fluids from the bottom of the unit's cabinet before returning equipment to service. The unit's leak detection circuit will alarm if any fluid remains after service.

Additional Information

Upon request DMS will provide the following: Circuit Diagrams, Component Parts List, Description of Components, Calibration Instructions, and any parts information needed for repair of the unit.

Routine Maintenance

Front Panel Removal

Remove the two screws, one on each side near the top of the panel, and pull the cover forward at the top. Unhook the ground wire that is attached to the front panel from the cabinet, and then lift the panel off of is mounting fingers to completely remove.

Firebox/Access Covers

Call DMS at 1-888-466-6633 prior to removing or servicing any components that require firebox/access covers to be removed. Removal of firebox/access covers will allow access to the electrical components underneath. Once removed the possibility of electrical shock is present. Use caution when performing any service to these components. Each unit has four firebox/access covers as described below:

Left-Side Dump Mechanism Access Cover

Located on the left side exterior of the cabinet. Note: This panel has a ground wire attached to it.

Right-Side Dump Mechanism Access Cover

Located on the right side exterior of the cabinet. Note: This panel has a ground wire attached to it.

Cold Water Board Cover

Located inside the unit on the right side panel above cold water manifold.

Main ICB and Power Supply Board Cover

Located inside the unit on the left side panel.

Inspections

Regularly visually inspect the unit for any signs of damaged or leaking components. If any problems are found, contact Customer Service at 1-888-466-6633 to report findings.

Replacement Items

Power Supply

There is not a substitute power supply replacement. The power supply must be replaced with the following:

- Manufacturer: Condor
- Model #: GLM75 Medical

Contact DMS for replacement parts at 1-888-466-6633.

Replacement Fuses

Two sets of replacement fuses are located on the main circuit board. Fuse specifications are as follows:

- Fuse Replacement for the main ICB- 250V 5A time delayed fuse.
- Fuse Replacement for the evacuation pump- 250 V 8A time delayed fuse.

Permanent Power Cord

Contact DMS for replacement only (see components part list), Procedure for replacement (correct connection & anchoring) are provided with the replacement power cord.

Spare Parts Kit

Part numbers for the unit's supplied parts kit is #TPSS Spare Parts 110. It contains the most common replacement parts for the unit and is located inside the TPSS's cabinet. The parts can be reordered at any time by contacting Customer Service at 1-888-466-6633.

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Fluid Path and Wiring Diagrams

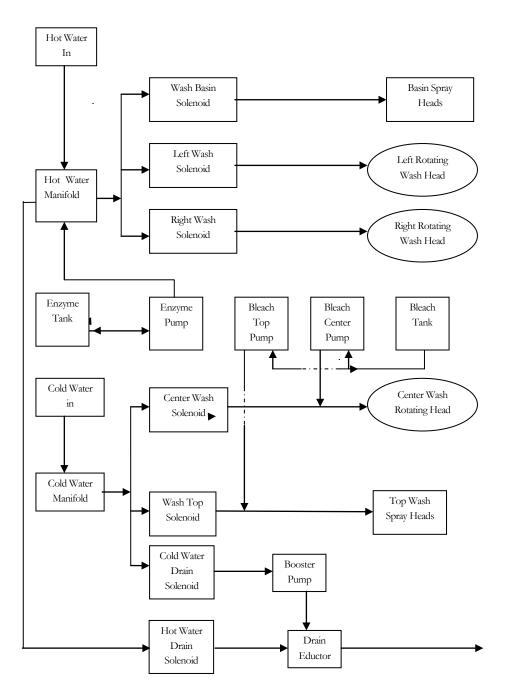
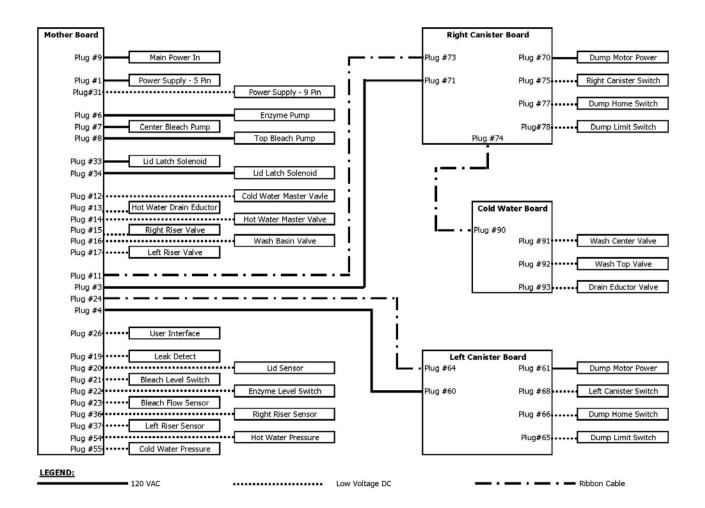


Figure 14 – Safety Station Fluid Delivery System





Preventative Maintenance

The TPSS Preventative Maintenance program consists of the inspection and repair or replacement of worn components starting on the sixth month of equipment operation and continuing thereafter on an annual basis. Items inspected during each schedule maintenance interval include the following:

Bleach Chemical Pumps Enzyme Chemical Pump Hot Water Solenoid Valves Cold Water Solenoid Valves Hot Water Master Valve Cold Water Master Valve Lid Seal Mechanical Spray Heads Lid Latch Mechanism Canister Rings Left Side Dump Mechanism Right Side Dump Mechanism Left Side Riser Detect Right Side Riser Detect Water and Drain Fittings Scale Preventers

		Year End			Required Parts	
Procedure	1	2	3	4	Part #	Quantity
Annual PM Kit*	Х	Х	Х	Х	PM-001	1
Replace Solenoid Valves		Х		Х	12028	9
Replace Rotating Spray Heads Assembly		Х		Х	91166	2
Replace Top Spray Heads	Х	Х	Х	Х	90484	4
Replace Basin Flat Spray Heads		Х		Х	90487	2
Lubricate Latch Pawl	Х	Х	Х	Х	No Parts Required	-

Table 3

TPSS Preventative Maintenance Schedule

*A list of parts contained in the Annual PM Kit is available by contacting Customer Service at 1-888-466-6633.

Notes: In a heavy use environment where more than 50 canisters are processed daily, preventative maintenance procedures may need to be completed more frequently. Excessive water hardness of 5 grains or above in facilities where scale preventers have not been installed voids the standard manufacturer's warranty and will increase preventative maintenance requirements.

Note: Preventative Maintenance Procedures are available upon request by contacting Customer Service at 1-888-466-6633.

Company Information

DMS has been helping healthcare facilities responsibly manage infectious fluid waste since 1997. Starting out as the premier manufacturer for fluid waste management systems in the country, we now have installations in leading healthcare facilities nation-wide.

DMS was founded in 1995. Products are manufactured and shipped from a centralized facility and supported by a nation-wide sales force. The company's principals include individuals with extensive backgrounds in product development, management, production, and sales of medical/surgical products. Jim Dunn, a successful inventor who served as an operating room nurse for 20 years, helped design DMS's products.

Contact Information

Dornoch Medical Systems, Inc.

Shipping Address: 200 NW Parkway Riverside, MO 64150

Office Correspondence: P.O. Box 681656 Riverside, MO 64168

> Toll free: 1-888-466-6633 Phone: 1-816-505-2226 Fax: 1-816-505-1050 Web: <u>www.dornoch.com</u>

Limited Warranty

Dornoch Medical Systems, Inc. (hereinafter 'DMS') warrants each new Transposal Product (as listed in the Transposal Product Guide, published by DMS from time to time) which is identified as "capital equipment" on the Purchase Agreement or Trial Agreement entered into in connection herewith, to be free from defects in materials and workmanship under normal use and service for a period of one (1) year from the date of installation (the "Term"). Both parts and labor are covered for the one-year period per the conditions below.

Notwithstanding the foregoing, if any Transposal Product requiring installation is not installed by a DMS Customer Service Engineer, the term of this limited warranty shall begin 14 days (two weeks) after the date the Transposal Product has been shipped by DMS. And for any Transposal Product which does not such installation, the Term of this limited warranty shall begin three (3) days after the date the Transposal Product has been shipped by DMS. Any replacement part, including a user-installed part that has been installed in accordance with instructions provided by DMS, is subject to this limited warranty for the period remaining in the Term for the subject Transposal Product.

NOTWITHSTANDING ANYTHING TO THE CONTRARY, DMS DOES NOT WARRANT ANY OF THE FOLLOWING THAT MAY BE SHIPPED WITH OR AN INTEGRAL PART OF ANY TRANSPOSAL PRODUCT OR SUPPLIES REQUIRED TO OPERATE OR INSTALL ANY TRANSPOSAL PRODUCT: (I) ITEMS AND PRODUCTS NOT MANUFACTURED BY DMS, INCLUDING, BUT NOT LIMITED TO ENZYMATIC CLEANER, TUBING, AND ANY BACKFLOW PREVENTER; (II) ITEMS AND PRODUCTS DESIGNED FOR SINGLE USE, INCLUDING BUT NOT LIMITED TO, CANISTER LIDS AND CART LIDS; AND (III) ITEMS AND PRODUCTS IDENTIFIED AS "CONSUMABLE/CONVERSION SUPPLIES" ON A PURCHASE AGREEMENT OR TRIAL AGREEMENT ENTERED INTO IN CONNECTION HEREWITH.

DMS' liability shall be limited, at its sole option and expense, to repair or replace during DMS' normal service hours any Transposal Product which has been examined by DMS and found, in the sole discretion of DMS, to be defective. The maximum liability of DMS to any person whatsoever arising out of or in connection with the sale or use of its equipment, whether such liability arises from a claim based upon contract, warranty, tort, or otherwise, shall in no case exceed the actual value of the equipment paid by the purchaser. DMS shall not be liable to the purchaser or to any other person or entity for incidental or consequential damages.

DMS reserves the right to replace defective parts or equipment with parts which may not be identical to the original equipment or parts. Said replacement parts or equipment shall be, in the judgment of DMS, equal to or better in performance than parts or equipment initially furnished.

THIS EXPRESS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE AND MERCHANTABILITY.

DMS reserves the right to discontinue any Transposal Product, incorporate new features, specifications, colors, etc., at any time without incurring obligations to provide similar equipment or features on previously sold models of equipment or parts.

This warranty applies to the original purchaser only and is not transferable, except to the end user in a lease financed transaction, and then, if and only if, and to the extent specifically approved by DMS in writing.

This limited warranty shall be construed and interpreted in accordance with and governed by the internal laws of the State of Missouri (without giving effect to Missouri choice or conflict of law principles).

PURCHASER IRREVOCABLY AGREES THAT, SUBJECT TO DMS' SOLE AND ABSOLUTE DISCRETION, ALL ACTIONS OR PROCEEDINGS IN ANY WAY ARISING OUT OF OR RELATED TO THIS LIMITED WARRANTY WILL BE LITIGATED IN COURTS HAVING SITUS IN KANSAS CITY, MISSOURI. PURCHASER HEREBY CONSENTS AND SUBMITS TO THE JURISDICTION OF ANY COURT LOCATED WITHIN MISSOURI.

THIS WARRANTY SHALL BE VOIDED IF (I) ANY PARTY OTHER THAN A DMS CUSTOMER SERVICE ENGINEER REPAIRS OR REPLACES OR ATTEMPTS TO REPAIR OR REPLACE ANY TRANSPOSAL PRODUCT OR PARTS AND DOES NOT FOLLOW SPECIFIC INSTRUCTIONS PROVIDED BY DMS FOR SUCH REPAIR OR REPLACEMENT OF PARTS OR (II) ANY TRANSPOSAL PRODUCT (A) IS NOT USED IN ACCORDANCE WITH INSTRUCTIONS PROVIDED BY DMS (including water hook-ups at hardness levels above five (5) grains per gallon), (B) IS NOT ACCORDED REASONABLE TREATMENT BY THE PURCHASER OR (C) IS USED IN A MANNER INCONSISTENT WITH THE FOLLOWING: TRANSPOSAL SAFETY STATIONS MUST NOT BE USED TO DISPOSE OF ANY SOLID MATERIAL, INCLUDING BUT NOT LIMITED TO NEEDLES, SYRINGES, HARDENED CASTING MATERIAL, TISSUE OR ANY OTHER SOLID OR SEMI-SOLID. SHOULD ANY TRANSPOSAL PRODUCT BE USED IN A MANNER INCONSISTENT WITH THE FOREGOING AND A DRAIN BLOCKAGE OCCURS, THE PURCHASER SHALL BE SOLELY RESPONSIBLE FOR THE COST OF ALL REPAIRS OF THE TRANSPOSAL EQUIPMENT AND OF ANY FACILITY DRAINAGE SYSTEMS AND ANY OTHER RELATED DAMAGE.